



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0317]

Yvelice Villaman-Bencosme: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debaring Yvelice Villaman-Bencosme from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Yvelice Villaman-Bencosme was convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of a drug product under the FD&C Act. Ms. Villaman-Bencosme was given notice of the proposed permanent debarment and was given an opportunity to request a hearing to show why she should not be debarred. As of December 13, 2021 (30 days after receipt of the notice), Ms. Villaman-Bencosme had not responded. Ms. Villaman-Bencosme's failure to respond and request a hearing constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, or at <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM-4029), Office of Strategic Planning and Operational Policy, Office of Regulatory

Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240-402-8743, debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(A) of the FD&C Act (21 U.S.C. 335a(a)(2)(A)) requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product under the FD&C Act. On March 19, 2021, Ms. Villaman-Bencosme was convicted as defined in section 306(l)(1) of the FD&C Act when judgment was entered against her in the U.S. District Court for the Southern District of Florida-Miami Division, after her plea of guilty, to one count of Conspiracy to Commit Wire Fraud in violation of 18 U.S.C. 1349.

The factual basis for this conviction is as follows: Ms. Villaman-Bencosme was a licensed medical doctor who served as a clinical investigator at Unlimited Medical Research, LLC from about September 2013 through June 2016. Ms. Villaman-Bencosme conspired with others to unlawfully enrich herself by making materially false representations about clinical trials; fabricating data and the participation of subjects in those clinical trials; concealing from FDA, sponsors, and contract research organizations the fact that the data and participation of subjects had been fabricated; and inducing sponsors and contract research organizations to pay money for Ms. Villaman-Bencosme and her co-conspirators' own benefit. On or about October 25, 2013, Ms. Villaman-Bencosme entered into a contract with a Contract Research Organization retained by a drug manufacturer (Sponsor) to serve as a clinical investigator for a clinical trial initiated by the Sponsor. The study was for an investigational drug intended to treat pediatric asthma in children between the ages of 4 and 11 years. As the clinical investigator Ms. Villaman-Bencosme was responsible for all aspects of the study to include ensuring that subjects

provided informed consent and understood the risks of participating in the study, reporting adverse events to the Sponsor, and maintaining honest and accurate records known as “case histories.” Instead, Ms. Villaman-Bencosme used personal identification information from pediatric patient medical records maintained at her private medical practice to falsify case histories. This included a number of false details. Ms. Villaman-Bencosme made it appear that: the study subjects satisfied the eligibility criteria to participate in the study; the subjects received a physical examination from her; the patients received the study drug at the study site; the patients returned the study drug to the study site; and the patients received payment for visits to the study site.

As a result of this conviction, FDA sent Ms. Villaman-Bencosme by certified mail on November 3, 2021, a notice proposing to permanently debar her from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(A) of the FD&C Act, that Ms. Villaman-Bencosme was convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product under the FD&C Act. The proposal also offered Ms. Villaman-Bencosme an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Ms. Villaman-Bencosme received the proposal on November 13, 2021. She did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and any contentions concerning her debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(A) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Ms. Villaman-Bencosme has been convicted of a felony under Federal

law for conduct relating to the development or approval, including the process of development or approval, of any drug product under the FD&C Act.

As a result of the foregoing finding, Ms. Villaman-Bencosme, is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see DATES) (see sections 306(a)(2)(A) and 306(c)(2)(A)(ii) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Ms. Villaman-Bencosme, in any capacity during her debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Ms. Villaman-Bencosme provides services in any capacity to a person with an approved or pending drug product application during her period of debarment, she will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug application from Ms. Villaman-Bencosme during her period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B) of the FD&C Act). Note that, for purposes of sections 306 and 307 of the FD&C Act, a “drug product” is defined as a “drug subject to regulation under section 505, 512, or 802 of this Act [(21 U.S.C. 355, 360b, 382)] or under section 351 of the Public Health Service Act [(42 U.S.C. 262)]” (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Any application by Ms. Villaman-Bencosme for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2021-N-0317 and sent to the Dockets Management Staff (see ADDRESSES). The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket and will be viewable at <https://www.regulations.gov> or at the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

Dated: April 12, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-08302 Filed: 4/18/2022 8:45 am; Publication Date: 4/19/2022]